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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,745	06/25/2003	Aaron Garzon	87754-7499	9969
28765	7590	05/20/2005	EXAMINER	
WINSTON & STRAWN LLP 1700 K STREET, N.W. WASHINGTON, DC 20006			OWENS, AMELIA A	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,745

Applicant(s)

GARZON ET AL.

Examiner

Amelia A. Owens

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,9-11,18 and 21-40 is/are rejected.
- 7) ☒ Claim(s) 3-8, 12-17, 19-20 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6-25-03;10-19-04;12-20-04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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Art Unit: 1625

DETAILED ACTION

Claims 1-40 are pending. Drawings were filed on June 25, 2003; October 19, 2004; December 20, 2004. Foreign priority has been claimed.

Information Disclosure Statement

The examiner has considered the IDS.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention: The nature of the invention is the method of treating or preventing inflammatory diseases or disorders damage resulting from ischemia, injuries to the central nervous system (CNS) and neurodegenerative disorders, pain, autoimmune diseases,

Art Unit: 1625

cardiovascular disorders or drug abuse, tolerance or dependence using the claimed compounds.

See claim 21.

The state of the prior art and predictability: The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize the difficulty in *treating or preventing inflammatory diseases or disorders damage resulting from ischemia, injuries to the central nervous system (CNS) and neurodegenerative disorders, pain, autoimmune diseases, cardiovascular disorders or drug abuse, tolerance or dependence* using a class of compounds or a single compound. No class of compounds or single compound has been found effective in treating, preventing such a myriad of unrelated diseases or disorders. Furthermore, applicant has not demonstrated that the claimed compounds are successful in treating, preventing, any of the named diseases or disorders. Therefore, applicants' statement at page 6 line 6 through page 7 line 15 is seen to be prophetic at best. The language merely describes applicants' intent for the compound. Applicant is invited to come in with a declaration utilizing the claimed compounds

Art Unit: 1625

showing positive *treatment, prevention* of one or more of the myriad of diseases or disorders listed.

Guidance and working examples: The compounds according to the invention have been prepared. The test data at pages 31-34 and 50-73 is noted. Further it is not clear that any of the tests correlate to treatment of any of the named disease. There is no evidence of functional treatment, i.e. no correlation to treatment in humans.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of claim 1 for the treatment and/or prevention of the myriad of diseases. As a result necessitating one of ordinary skill to perform an exhaustive search for which diseases can be treated by which compound of claim 1 in order to practice the claimed invention.

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, one of ordinary skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compounds and which diseases can be prevented by the compounds of the instant claims, with no assurance of success.

This rejection can be overcome by deleting the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2,10,11,21,22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims contain the language ‘...carbon side chain comprising 1-8 carbon atoms interrupted by 1-3 heteroatoms; or ...heterocyclic moiety having from 5-20 atoms

Art Unit: 1625

comprising.....3-8 carbons interrupted by 0-4 heteroatoms...selected from the group consisting of N, O, and S;...'. It is unclear what is the structure the terms are defining. What for example is a carbon chain interrupted by a heteroatom? Is it an alkoxy, thiol, amine? What is a heterocyclic moiety ... having 3-8 carbons interrupted by 0-4 heteroatoms? If there are zero heteroatoms then it is no longer a heterocycle? No chemical structure can be associated with such terms.

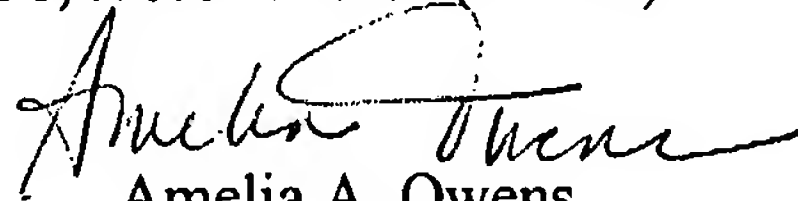
Claims 9,18 and 29 do not end in proper Markush format. Note, it is just a listing of compounds.

Claims 3-8, 12-17, 19, 20, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Amelia A. Owens
Primary Examiner
Art Unit 1625